UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. GENENTECH, INC., Defendant.	Civil Action No. 11-CV-01156 (VB) ECF Case Jury Demand

AMENDED ANSWER AND COUNTERCLAIM

Genentech, Inc. ("Genentech") files this amended answer and counterclaim in response to the Complaint filed by Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron").

"NATURE OF THIS ACTION"

1. Genentech admits that Regeneron purports to have brought this action under 28 U.S.C. §§ 1331, 2201, and 2202, and 35 U.S.C. § 100 *et seq*. In all other respects, Genentech denies the allegations in Paragraph 1 of the Complaint.

2. Genentech admits that Regeneron purports to seek a declaration in this action relating to U.S. Patent Nos. 5,952,199; 6,100,071; 6,383,486; 6,897,294; and 7,771,721. In all other respects, Genentech denies the allegations in Paragraph 2 of the Complaint.

"THE PARTIES"

3. Genentech admits that Regeneron purports to be a corporation organized and existing under the laws of the State of New York with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the remaining allegations in Paragraph 3 of the Complaint and on that basis denies them.

4. Genentech denies that Regeneron scientists discovered a novel pharmaceutical referred to in the Complaint as VEGF Trap. Genentech admits that the VEGF Trap is in clinical development for ophthalmologic and oncology indications. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the remaining allegations in Paragraph 4 of the Complaint and on that basis denies them.

5. Genentech admits the allegations in Paragraph 5 of the Complaint.

6. Genentech admits that it has been and currently is licensed to do business in the State of New York, and that it has and currently does business in the State of New York. Genentech admits that it has sold and continues to offer for sale and sells products in the State of New York and within this judicial district. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the remaining allegations in Paragraph 6 of the Complaint and on that basis denies them.

"JURISDICTION AND VENUE"

7. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Genentech admits the allegations in Paragraph 7 of the Complaint.

8. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Genentech admits that venue is proper under 28 U.S.C. §§ 1391(b) & (c) because Genentech admits that this Court had personal jurisdiction over Genentech for the purposes of this action at the time the action was commenced.

"INTRA-DISTRICT ASSIGNMENT"

9. Genentech admits that Regeneron resides in Westchester County. Genentech denies the remaining allegations in Paragraph 9 of the Complaint.

"BACKGROUND"

"DEVELOPMENT OF THE VEGF TRAP"

10. Genentech admits that Regeneron purports to have filed in 2007 a Phase III clinical trial for the use of VEGF Trap in the treatment of neovascular wet age-related macular degeneration, that Phase III studies may be used to develop data to support a Biologics License Application for the United States Food and Drug Administration, and that a Biologics License Application is necessary to secure approval to market a drug in commerce in the United States. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the remaining allegations in Paragraph 10 of the Complaint and on that basis denies them.

11. Genentech admits that on November 22, 2010, Regeneron issued a press release regarding the results of purported Phase III studies for VEGF Trap relating to wet age-related macular degeneration.

12. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the allegations in Paragraph 12 of the Complaint and on that basis denies them.

13. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the allegations in Paragraph 13 of the Complaint and on that basis denies them.

14. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the allegations in Paragraph 14 of the Complaint and on that basis denies them.

15. Genentech lacks knowledge and information sufficient to form a belief as to the truthfulness of the allegations in Paragraph 15 of the Complaint and on that basis denies them.

"GENENTECH'S DAVIS-SMYTH PATENTS"

16. Genentech admits the allegations in Paragraph 16 of the Complaint.

17. Genentech admits that Regeneron's publicly-available filings with the United States Securities and Exchange Commission contain the statements reflected in Paragraph 17 of the Complaint.

18. Genentech admits that it maintains that VEGF Trap infringes one or more of the Davis-Smyth patents. Genentech also admits that: after Regeneron filed a declaratory judgment complaint against Genentech on November 19, 2010, relating to non-infringement of the Davis-Smyth patents, Regeneron, by letter dated December 22, 2010, asked Genentech for a covenant not to sue regarding those patents; and Genentech subsequently responded that because of Regeneron's complaint, any discussions must involve the parties' attorneys, and invited Regeneron to contact Genentech's general counsel for further discussion. Genentech also admits that Arthur Levinson referred to Regeneron's discussion in Regeneron's own SEC filings of the Davis-Smyth patents when responding to questions by investors. Genentech denies the remaining allegations of Paragraph 18 of the Complaint.

19. Genentech denies the allegations in Paragraph 19 as of the date this Complaint was filed.

"CLAIM FOR RELIEF"

"(Declaratory Judgment of Non-Infringement and/or Invalidity of the Genentech Davis-Smyth Patents)"

20. Genentech incorporates by reference its answers to the allegations of paragraphs 1 through 19.

21. Genentech admits that Regeneron seeks a judicial declaration that no acts by any entity related to the VEGF Trap do or will directly infringe or infringe under the doctrine of equivalents, or contribute to or induce the infringement of, any valid claim of U.S. Patent Nos. 5,952,199, 6,100,071, 6,383,486, 6,897,294, and 7,771,721, but denies that Regeneron is entitled

to such a judicial declaration. Genentech denies the remaining allegations of Paragraph 21 of the Complaint.

"PRAYER FOR RELIEF"

Genentech denies that Regeneron is entitled to the relief requested or any other relief.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

22. Regeneron's claims are barred, in whole or in part, as Regeneron has not stated a claim upon which relief can be granted.

RIGHT TO ASSERT ADDITIONAL DEFENSES

23. Genentech reserves the right to assert and pursue additional defenses.

DEMAND FOR A JURY TRIAL ON ALL DEFENSES

24. Genentech demands trial by jury on all defenses and issues triable by jury.

AMENDED COUNTERCLAIM

For its counterclaim against Regeneron, Counter-Plaintiff Genentech alleges as follows:

PARTIES

25. Counter-Plaintiff Genentech, Inc. is a corporation organized under the laws of Delaware, with its principal place of business in South San Francisco, California. Genentech is registered to do business and is doing business in the State of New York.

26. Counter-Defendant Regeneron, Inc. is a corporation organized under the laws of the State of New York and lists its principal place of business as 777 Old Saw Mill River Road, Tarrytown, New York.

JURISDICTION AND VENUE

27. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and jurisdiction is therefore properly based on Title 35 of the United States Code, § 271, and Title 28 of the United States Code, § 1338(a).

28. This Court has personal jurisdiction over Regeneron by virtue of, *inter alia*, its residing in the State of New York.

29. Venue is proper in this District pursuant to Title 28, United States Code, §§ 1391(c) and 1400(b).

THE DAVIS-SMYTH PATENTS

30. U.S. Patent No. 5,952,199, titled Chimeric Receptors as Inhibitors of Vascular Endothelial Growth Factor Activity, And Processes for Their Production, was issued by the U.S. Patent and Trademark Office on September 14, 1999. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

31. U.S. Patent No. 6,100,071, titled Receptors as Novel Inhibitors of Vascular Endothelial Growth Factor Activity And Processes for Their Production, was issued by the U.S. Patent and Trademark Office on August 8, 2000. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

32. U.S. Patent No. 6,383,486, titled Inhibitors of Vascular Endothelial Growth Factor Activity, Their Uses And Processes for Their Production, was issued by the U.S. Patent and Trademark Office on May 7, 2002. The inventors on the patent are Terri Lynn Davis-

Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

33. U.S. Patent No. 6,897,294, titled Inhibitors of Vascular Endothelial Growth Factor Activity, Their Uses And Processes for Their Production, was issued by the U.S. Patent and Trademark Office on May 24, 2005. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

34. U.S. Patent No. 7,771,721, titled Methods for Using Chimeric Vascular Endothelial Growth Factor Receptor Proteins, was issued by the U.S. Patent and Trademark Office on August 10, 2010. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

35. The 5,952,199, 6,100,071, 6,383,486, 6,897,294, and 7,771,721 patents will be referred to herein as the "Davis-Smyth patents."

36. Genentech owns all rights, title, and interest in and to the Davis-Smyth patents.

37. On information and belief, Regeneron has known about the '199, '071 and/or '486 patents at least since March 3, 2005 and has known about the '294 and '721 patents at least since they issued on May 24, 2005 and August 10, 2010, respectively.

VEGF Trap-Eye

38. On information and belief, Regeneron's VEGF Trap-Eye product is a protein, the amino acid sequence of which is in part derived from the human VEGF Receptor 1 ("VEGFR1" or "FLT-1"), the human VEGF Receptor 2 ("VEGFR2" or "KDR"), and human immunoglobulin G1.

39. On information and belief, Regeneron's VEGF Trap-Eye product was and is designed to bind VEGF and, in turn, treat disease states characterized by undesirable angiogenesis and/or neovascularization.

40. On information and belief, Regeneron has filed a BLA with the FDA, seeking approval to market VEGF Trap-Eye in the U.S. for use in treating wet age-related macular degeneration.

41. On information and belief, Regeneron: a) has made, used, offered for sale, sold and/or marketed; b) is making, using, offering for sale, selling and/or marketing; and/or c) is preparing to make, use, offer for sale, sell, and/or market VEGF Trap-Eye in the United States, including within this judicial district.

42. On information and belief, Regeneron has taken concrete and substantial steps to prepare for commercial manufacturing, marketing, and selling of VEGF Trap-Eye throughout the United States, including within this judicial district.

43. On information and belief, Regeneron is manufacturing VEGF Trap-Eye in the United States.

COUNT I
(Infringement of the '071 patent)

44. Genentech incorporates the allegations in Paragraphs 25-43 as if fully set forth herein.

45. By virtue of Regeneron: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market VEGF Trap-Eye in the United States, Regeneron has infringed, is infringing and/or will infringe—directly, and/or by contributing to others'

infringement of and/or by inducing others to infringe—one or more claims of the '071 patent, either literally and/or under the doctrine of equivalents.

46. Regeneron's past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover from Regeneron the damages resulting from Regeneron's wrongful acts in an amount to be determined at trial, but no less than a reasonable royalty.

47. Regeneron's infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

48. Regeneron's infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Counter-Defendant's infringement is enjoined by this Court.

COUNT II
(Infringement of the '486 patent)

49. Genentech incorporates the allegations in Paragraphs 25-48 as if fully set forth herein.

50. By virtue of Regeneron: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market VEGF Trap-Eye in the United States, Regeneron has infringed, is infringing and/or will infringe—directly, and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the '486 patent, either literally and/or under the doctrine of equivalents.

51. Regeneron's past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover from Regeneron the damages

resulting from Regeneron's wrongful acts in an amount to be determined at trial, but no less than a reasonable royalty.

52. Regeneron's infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

53. Regeneron's infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Counter-Defendant's infringement is enjoined by this Court.

COUNT III
(Infringement of the'294 patent)

54. Genentech incorporates the allegations in Paragraphs 25-53 as if fully set forth herein.

55. By virtue of Regeneron: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market VEGF Trap-Eye in the United States, Regeneron has infringed, is infringing and/or will infringe—directly, and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the '294 patent, either literally and/or under the doctrine of equivalents.

56. Regeneron's past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover from Regeneron the damages resulting from Regeneron's wrongful acts in an amount to be determined at trial, but no less than a reasonable royalty.

57. Regeneron's infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

58. Regeneron's infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Counter-Defendant's infringement is enjoined by this Court.

COUNT IV
(Infringement of the'721 patent)

59. Genentech incorporates the allegations in Paragraphs 25-58 as if fully set forth herein.

60. By virtue of Regeneron: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market VEGF Trap-Eye in the United States, Regeneron has infringed, is infringing and/or will infringe—directly, and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the'721 patent, either literally and/or under the doctrine of equivalents.

61. Regeneron's past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover from Regeneron the damages resulting from Regeneron's wrongful acts in an amount to be determined at trial, but no less than a reasonable royalty.

62. Regeneron's infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

63. Regeneron's infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Counter-Defendant's infringement is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Genentech requests that judgment be entered in its favor against Regeneron:

1. Finding that Regeneron: a) has directly infringed and/or will directly infringe; b) has actively induced and/or will actively induce others to infringe, and/or c) has engaged and/or will engage in acts that contribute to others infringing one or more claims of the '071, '486, '294, and '721 patents;

2. Finding that Regeneron's infringement of the '071, '486, '294, and '721 patents was and/or is willful and deliberate;

3. If appropriate, taking into account the interests of patients, enjoining Regeneron and its officers, agents, servants, employees, parents, subsidiaries, affiliates, successors, assignees, licensees, and attorneys, and all persons acting in concert or participation with them, from infringing the '071, '486, '294, and '721 patents directly, by contributory infringement, and/or by actively inducing infringement;

4. Ordering Regeneron to account for and pay to Genentech any and all damages caused by the infringement of one or more claims of the '071, '486, '294, and '721 patents;

5. Ordering Regeneron to pay increased damages, up to treble damages to Genentech because of the willful nature of Regeneron's infringement of one or more claims of the '071, '486, '294, and '721 patents;

6. Ordering that this case be declared an exceptional case under 35 U.S.C. § 285 and that Genentech be awarded its attorney's fees incurred in this action;

7. Ordering an award of Genentech's costs and expenses for this action, pre- and post-judgment interest on any money damages award, and any other charges to the maximum extent permitted;

8. Ordering such future relief as the Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Genentech demands a trial by jury of all issues so triable.

Dated: May 11, 2011

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